Remarks

Originally pending were claims 1-14. In the Office Action, the original claims were rejected under 35 USC § 112, second paragraph, for various informalities. Claims 1-14 have been cancelled by this paper, thus obviating the § 112 rejection.

Original claims 1-14 were also rejected on prior art grounds under 35 USC § 102 as being anticipated by Purdie ('894), a reference to which Applicant is obviously familiar.

It being evident that the originally submitted claims were confusing with respect to the subject matter being claimed, Applicant has cancelled the original claims and substituted therefor new claims 15-29. The new claims serve to better define the present invention over the subject matter disclosed in the '894 patent.

New independent claim 15 clearly sets out that the assay procedure is a comprehensive serum assay of unsaturated cyclic and open chain aliphatic molecular structures which renders a profile that discriminates among cholesterol *and* non-cholesterol long chain fatty acids, such as triglycerides, phospholipids, saturated and unsaturated cholesteryl-LCFA esters and free long chain fatty acids. This is notably different from the assay procedure described in the '894 patent, which is cholesterol specific, as explained in detail in the instant specification, to wit:

> In United States Patents 5,593,894 and 5,989,916, incorporated herein by reference, speciation of serum cholesterol over the very low density lipoprotein (VLDL), low density lipoprotein (LDL), and high density lipoprotein (HDL) fractions was done in a direct manner based upon a multivariate analysis treatment of visible absorbance data produced by

> simultaneous color derivatizations of the serum cholesterol lipoprotein subfractions. Total serum cholesterol (TC) was determined as the sum of the amounts in each fraction. (p. 1, lines 7-13)
>
> Data analyses claimed in Patents 5,593,894 and 5,989,916 were limited to the simultaneous assays of three cholesterol variables, namely VLDL-C, LDL-C, and HDL-C, using absorbance data at only five wavelengths and the single reagent system, acetyl chloride and $HClO_4$ catalyst. TC values were calculated as the sums of the parts. (p. 2, lines 11-14)
>
> Implications that other serum lipids (e.g. triglycerides and free fatty acids) are involved in the genesis of coronary heart disease (CHD), and appear to react with the same derivatizing reagent, stimulated the need for developing broader simultaneous assays of multiple variables but still using a single experimental procedure. (p. 2, lines 15-18)
>
> [In connection with the present invention] It was determined that the chromogenic acylating reagent(s), originally thought to be selective to only cholesterol, is also selective towards particular -CH=CH- double bonds that are present in both cyclic and open chain aliphatic molecular structures. In serum, therefore, the actual number of lipid analytes that do react with the acylating reagent is extended to include free cholesterol (FC); saturated and unsaturated cholesteryl-LCFA esters (CE); free LCFA's themselves; and LCFA's in the form of triglycerides (TG) and phospholipids (PL), both of which are unsaturated LCFA esters of glycerol. Saturated LCFA's do not react. (p. 3, lines 7-14)

Thus, it can be appreciated that the presently claimed invention is indeed patentably distinct from the prior patented subject matter in breadth of assay.

Additionally, new claim 15 includes measuring the spectral characteristics of the sample over substantially the entire visible wavelength range to obtain multiplexed spectral data, as opposed to the procedure previously taught which used absorbance data at only five wavelengths. This is significant insofar as the major absorbance bands in the spectra for colored derivatives of standard reference materials of cholesterol and its esters occur at wavelengths longer than the major bands for colored derivatives of standard

reference materials of mono and poly-unsaturated fatty acids, whether they are in the forms of free acids or esters of cholesterol or glycerol. (see Spec., p. 14, lines 2-5 and Table 1) Thus, the presently claimed invention further defines over the prior art.

Still further, in light of Applicant's discovery that it is possible to expand the diagnostic capabilities of the color inducing reaction from being only a serum cholesterol lipoprotein profile to a much broader serum lipids assay, it is made possible to utilize the multiplexed spectral data to diagnose or evaluate risk factors among the different serum dyslipidemias, diabetes and coronary artery disease. New claims 16-19 include this previously unknown concept and, thus, are believed to distinguish over the prior art in this additional respect.

New claims 20-29, which present a variety of preferred aspects and conditions, all depend directly or indirectly from claim 15. The patentability of these claims follows *a fortiori* from claim 15.

Considering the foregoing, it is sincerely believed that this case is in a condition for allowance, which is respectfully requested.

* * * * *

This paper is intended to constitute a complete response to the outstanding Office Action. Please contact the undersigned if it appears that a portion of this response is missing or if there remain any additional matters to resolve. If the Examiner feels that processing of the application can be expedited in any respect by a personal conference, please consider this an invitation to contact the undersigned by phone.

Respectfully submitted,

10/27/03
DATE

SIGNATURE OF PRACTITIONER

Reg. No.: 36,050

R. Alan Weeks
(type or print name of practitioner)

Tel. No.: (918) 599-0621

321 S. Boston Ave., Suite 800
P.O. Address

Customer No.: 22206

Tulsa, OK 74103-3318

(Word 229103.1)